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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,585	07/30/2001	Tian-Qiang Sun	PP-16093.002	2590

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,585	SUN ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of claim 1, Paper of 11/24/2003, is acknowledged. Claims 1-25 are at issue and are present for examination. Applicants' arguments filed on 11/24/2003, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 7-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

Applicants filing of information disclosure, filed 8/6/2003, is acknowledged. Those references considered have been initialed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (2-6 dependent on) is indefinite in that it is vague and confusing in the recitation in part (s) "...except for a conversion of a conserved lysine to an alanine at an ATP binding site of the encoded amino acid sequence" . It is vague and unclear what

applicants consider to be an ATP binding site of the sequences of (c) and (d) (i.e. SEQ ID NO: 6).

In response to this previous rejection applicants have amended claims 1 and submit that without acquiescing to the ground of rejection, applicants amendment is not subject to the specific grounds of objection ("about" language and "ATP binding site"). Applicants comments and amendment are acknowledged, however the rejection is maintained, in light of applicants have not explained why the ATP binding site of the sequences of SEQ ID NO: 6 is not unclear.

Newly amended claim 1 (2-6 dependent on) is indefinite in that part (h) and (i) each recite "sequences of (a)-(b), and then go on to attempt to change the referred to sequence. This is unclear and confusing since each of the referred to sequences of (a) and (b) are drawn to sequences (i.e. that of SEQ ID NO: 6) that if changed would no longer be SEQ ID NO: 6. Thus it is unclear what applicants intent is in each of these parts of the claim. It is further noted and as an example, that part (h) recites "sequences of (a)-(b) wherein said sequence encodes a polypeptide of SEQ ID NO: 6 with at least one amino acid substitution, wherein said polypeptide has kinase activity". Such a claim limitation effectively reads on **any** and **all** kinases with the exception of SEQ ID NO: 6.

Newly amended claim 1 (2-6 dependent on) is indefinite in that part (j) and (k) are each indefinite in that they are unclear and confusing as they do not appear to further limit the genus of sequences from which they depend.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it applied to previous claims 1-6. In response to the rejection applicants have amended claim 1 and traverse this rejection as it applies to the newly rejected claims.

Applicants submit that the examiner recommended adding functional language to the rejected claims and that the amended claims address this issue.

Applicants amendment and argument is not found persuasive because while applicants have added "functional language" to specific subsections of the claim such as part (e), it remains that this added "functional language" merely describes but a small portion of the claimed molecules. Further even if applicants were to amend the claims such that the entire genus claimed had the discussed functional limitation, it remains that certain portions of the claim still require additional structural characterization to adequately describe them. As stated in the previous office action, applicant is advised to in **addition to more structural detail**, adding functional language to the rejected claims such that an adequate structure to function/activity relationship of the claimed genus is described.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising a polynucleotide sequence encoding SEQ ID NO: 6, does not reasonably provide enablement for any nucleic acid molecule comprising a polynucleotide sequence at least 95% identical to a sequence encoding SEQ ID NO: 6, or sequence that is a mere 100 or 500 contiguous nucleotides of the coding region of SEQ ID NO: 4, or any sequence except for at least one amino acid substitution in the encoded amino acid sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 1-6. In response to the rejection applicants have amended claim 1 and traverse this rejection as it applies to the newly rejected claims.

Applicants submit that the amount of experimentation that may be required to practice the present invention does not rise to the level of being undue experimentation as defined by the court in Wands.

Applicants submit that applying the eight Wands factors, one of skill in the art would conclude that undue experimentation would not be required to practice the

claimed invention. In so doing so applicants submit arguments under headings of each of the wands factors. Applicants submit that the quantity of experimentation necessary: is not undue as one can use a hybridization probe to locate and obtain hybridizing DNA, which can be tested for activity. Applicants submit that the amount of direction or guidance presented by the specification is sufficient, and that applicants describe examples of a transfection/transformation of a claimed polynucleotide. Applicants submit that the nature of the invention is such that applicants have cloned a human homologue of the PAR-1 gene and that the prior art provides methods and materials and the level of skill in the art is high. Finally applicants submit that the art is predictable and the breadth of the claim(s) routinely identified and/or constructed.

Applicants argument is not found persuasive for the reasons previously stated. The claims rejected under this section of U.S.C. 112, first paragraph, place minor structural limits on the claimed nucleic acid molecules such that adequate guidance is disclosed with respect to how to make and use the majority of the scope of the claimed genus. Applicants are reminded that the claimed genus of polynucleotides encompasses any polynucleotide which meets the minor structural limitations of the claims (i.e. see parts d, f. g and h), and most of the encompassed molecules have no structural limitation.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any nucleic acid molecule comprising a polynucleotide sequence that is a mere 100 or 500 contiguous nucleotides of the coding region of SEQ ID NO: 4, because the specification does not establish: (A) regions of the

protein and thus polynucleotide structure which may be modified without effecting its activity; (B) the general tolerance of serine/threonine protein kinases and their encoding polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a serine/threonine protein kinases with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain a function/activity of the claimed polynucleotides or their encoded polypeptides and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable it would require undue experimentation for one skilled in the art to **arrive at and use** the majority of those polynucleotides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any polynucleotide encoding SEQ ID NO: 6. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Espinosa et al., (Human serine/threonine protein kinase EMK1: genomic structure and cDNA cloning of isoforms produced by alternative splicing, Cytogenet. Cell Genet., Vol 81, No 3/4, pages 278-282, 1998, Ref V, enclosed 892) as evidenced by Espinosa et al. (Genbank Accession Number X97630, October 1998).

The rejection was stated in the previous office action and repeated below for applicants convenience.

Espinosa et al. teach isolation and cloning of a polynucleotide that encodes two isoforms of the human serine/threonine protein kinase EMK1 and Espinosa et al. teach vectors and host cells comprising said polynucleotide and methods of making said vectors and host cells. The polynucleotide isolated, cloned and disclosed by Espinosa et al. has a best local similarity score of greater then 92% when compared to the sequence of SEQ ID NO: 4 and the taught nucleic acid comprises polynucleotide sequences of at least 500 contiguous nucleotides of the coding region of SEQ ID NO: 4, as evidenced by Espinosa et al. (Genbank Accession Number X97630, October 1998).

Therefore, Espinosa et al. anticipates claims 1-6.

In response to this rejectin applicants have amended claim 1 and submit that the claims as amended are not subject to the ground of this rejection. Applicants comments are noted, however, the rejection remains. Applicants attention is drawn to amended claim 1 parts (d), (f), (g) (h), (j) and (k), (See above 112 second paragraph rejection also) all of which remain anticipated by Espinosa et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
2/13/2004